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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,855	03/31/2006	Zhen Zhu	062331-5003	5375

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EXAMINER	
ZHENG, LI	
ART UNIT	PAPER NUMBER
1638	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,855	ZHU ET AL.	
	Examiner	Art Unit	
	LI ZHENG	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 are pending and examined on the merits.

Specification

2. The specification is objected to because of the recitation of "a mino" on page 6, line 24.

Claim Objections

3. Applicant is advised that should claim 1 be found allowable, claims 7 and 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation "rare codons" render the claims indefinite. The recitation is a relative term with no definite meaning. It is unclear what is considered as "rare codons". The metes and bounds are not clear.

Further, claim 1 recites the limitation "the gene silencing" in part d). There is insufficient antecedent basis for this limitation in the claim.

Claims 7 and 8 provides for the use of the method of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7 and 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for breeding transgenic plant with high antiviral property by transforming the plants with recombinant vector in which the target gene is mutated by replacing some codons with rare synonymous codons.

The office interprets that the claims encompass modifying any target gene.

The specification teaches codon modification of the coat protein gene of the Potato Virus X (PVX) (specification, paragraph [0025]-[0028]). The specification further teach that there are more plants exhibiting the complete immunity or the highly resistant symptom in the transgenic tobacco plants transformed with the modified coat protein gene of PVX, compared with the transgenic tobacco plants transformed with the unmodified coat protein gene of PVX (specification, paragraph [0036].

Applicants do not describe any other target protein from any other viruses. Applicants also do not correlate the function of increasing viral resistance of a plant with any other target genes except for the coat protein gene of PVX.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of target genes, when modified by incorporating rare codons could render transgenic plants expressing the modified target gene with high antiviral property. The only species in claimed genus described in the specification is the coat protein from PVX. Applicants also do not disclose structural features common to members of the claimed genus. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for breeding transgenic tobacco plants with high antiviral property against PVX by transforming the tobacco plants with a recombinant vector in which the coat protein gene of PVX is mutated by replacing some codons with rare synonymous codons, does not reasonably provide enablement for any target gene capable of conferring viral resistance to any virus in any host plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for breeding transgenic plants with high antiviral property by transforming the plants with recombinant vector in which the target gene is mutated by replacing some codons with rare synonymous codons.

The office interprets the claims to encompass any target gene capable of conferring viral resistance to any virus in any host plant.

The specification teaches codon modification of the coat protein gene of the Potato Virus X (PVX) (specification, paragraph [0025]-[0028]). The specification further teach that there are more plants exhibiting complete immunity or the highly resistant symptom in the transgenic tobacco plants transformed with a codon modified coat protein gene of PVX, compared with the transgenic tobacco plants transformed with the unmodified coat protein gene of PVX (specification, paragraph [0036]).

Applicants do not describe any other target proteins from any other viruses. Applicants also do not correlate the function of increasing viral resistance of plant with any other target genes except for the coat protein gene of PVX.

Further, the specification does not provide guidance on how to get rare codons from a given plant. For example, the specification does not provide guidance on how many codons need to be sampled and which genes can be used for such purpose. The specification also does not provide guidance on what is the cut-off usage for being a rare codon.

The mechanism of how rare codons regulate mRNA stability or protein translation in plant is not well known. Van Hoof et al. (1997, Plant Molecular Biology 35:383-387) teach that rare codons are not sufficient to destabilize a transcript in tobacco (at least abstract) and that rare codons may need to be present at a specific location within the coding region in order to have a direct effect on mRNA stability (page 386, 1st paragraph of right column).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate and sequence the multitude of non-exemplified genes from any plant, to determine the rare codons in a given plant, to determine the location where the rare codons need to be present, to identify target gene from any organism to be modified, to produce expression vectors expressing modified target gene, and to transform any host plants therewith, in order to identify those, if any, that when over-expressed have enhanced viral resistance. See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention in full scope.

Conclusion

No claim is allowed. However, claims 1-8 are deemed free of prior art due to the failure of the prior at to teach or fairly suggest a method for breeding transgenic plants with high antiviral property by transforming the plants with recombinant vector in which the target gene is mutated by replacing some codons with rare synonymous codons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Primary Examiner, Art Unit 1638